# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

AbbVie, Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, Allegan Sales, LLC,

Plaintiffs,

v.

Keith M. Ellison,

Defendant.

AstraZeneca Pharmaceuticals LP Civil No. 24-2621(DSD/TNL)

Civil No. 24-2605(DSD/TNL)

Plaintiff,

v.

Keith M. Ellison, Ronda Chakolis, Kendra Mets, James Bilake, Amy Paradis, Ben Maisenbach, Rabih Nahas, Michael Haaq, John M. Zwier, Barbara Droher Kline,

Defendants.

This matter is before the court upon the motions to dismiss by defendants in the two above-captioned matters. The court has consolidated the cases for purposes of the pending motions given the similar issues raised. Based on a review of the file, record, and proceedings herein, and for the following reasons, the motions are granted.

#### **BACKGROUND**

This dispute arises from plaintiffs' challenge to the constitutionality of Minnesota Statute § 62J.96, which requires pharmaceutical manufacturers to offer discounted pricing mandated by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, to an unlimited number of "contract pharmacies" and as a condition to participating in Medicaid. AbbVie Am. Compl. ¶ 12; AstraZeneca Am. Compl. ¶ 4. Plaintiffs contend that in doing so, § 62J.96 effectively expands the scope of §340B coverage by forcing manufacturers to provide discounted drugs for sales occurring through contract pharmacies contrary to § 340B's plain language and federal case law. AbbVie Am. Compl. ¶ 12; AstraZeneca Am.

 $<sup>^1</sup>$  "Contract pharmacies" are pharmacies "under contract with a 340B covered entity to receive and dispense covered outpatient drugs on behalf of the covered entity." AbbVie Am Compl. § 12.

<sup>2</sup> The statutory scheme is complex and will be discussed only in enough to detail to provide context for the issues raised in defendants' motions.

Compl.  $\P$  4.

Plaintiffs AbbVie, Inc., AstraZeneca Pharmaceuticals LP, Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, and Allegan Sales, LLC are drug manufacturers. AbbVie Am. Compl. ¶¶ 19-25; AstraZeneca Am. Compl. ¶¶ 15. Plaintiffs sue defendant Keith Ellison in his official capacity as the Attorney General of Minnesota. AbbVie Am. Compl. ¶¶ 26; AstraZeneca Am. Compl. ¶¶ 16. AstraZeneca also sues Ronda Chakolis, Kendra Mets, James Bilake, Amy Paradis, Ben Maisenbach, Rabih Nahas, Michael Haag, John M. Zwier, and Barbara Droher Kline, in their official capacities as members of the Minnesota Board of Pharmacy. AstraZeneca Am. Compl. ¶¶ 17-25.

In early July 2024, plaintiffs filed suit against the Attorney General and the BOP, alleging various constitutional claims and seeking declaratory and injunctive relief. In August 2024, plaintiffs filed amended complaints. Abbie alleges preemption under the Sixth Amendment's Supremacy Clause; violation of the Fourth Amendment's Takings Clause; and violation of the Fourteenth Amendment's Due Process Clause. AbbVie Am. Compl. ¶¶ 109-133.

<sup>&</sup>lt;sup>3</sup> The court will refer to the drug manufactures collectively as "plaintiffs" unless a finer distinction is required.

 $<sup>^{4}\,\</sup>mbox{The}$  court will refer to the pharmacy board members collectively as "BOP."

AstraZeneca similarly alleges preemption and violation of the Takings Clause. AstraZeneca Am. Compl.  $\P\P$  91-94, 101-06. AstraZeneca also alleges violation of Article One's Contracts Clause. Id.  $\P\P$  95-100.

Plaintiffs have sued the Attorney General because, in his role as Attorney General, "he has the responsibility to enforce the laws of the state, including [§ 62J.96], pursuant to his constitutional duties[.]" AbbVie Am. Compl. ¶ 26; see also AstraZeneca Am. Compl. ¶ 16. As to the BOP, AstraZeneca contends that it also "enforces the challenged legislation." AstraZeneca Am. Compl. ¶¶ 17-25. Plaintiffs asks the court to enjoin the Attorney General and the BOP from enforcing § 62J.96 given its unconstitutionality. Plaintiffs do not allege that any enforcement action has been undertaken, nor do they allege that enforcement has been threatened by either defendant.

Defendants now move to dismiss on various grounds.

Defendants' positions have been supported by amici curiae. See

AbbVie ECF No. 34; AstraZeneca ECF No. 37.

### **DISCUSSION**

### I. Standard of Review

To survive a motion to dismiss for failure to state a claim,

"'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'"

Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 594 (8th Cir. 2009)

(quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff [has pleaded] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007)). Although a complaint need not contain detailed factual allegations, it must raise a right to relief above the speculative level. Twombly, 550 U.S. at 555. "[L]abels and conclusions or a formulaic recitation of the elements of a cause of action" are not sufficient to state a claim. Iqbal, 556 U.S. at 678 (citation and internal quotation marks omitted).

## II. Standing/Eleventh Amendment Immunity

Article III of the United States Constitution limits the jurisdiction of federal courts to justiciable cases and controversies. U.S. Const. art. III, § 2; <u>Lujan v. Defenders of Wildlife</u>, 504 U.S. 555, 559-60 (1992). Standing is an "essential and unchanging part of the case-or-controversy requirement of Article III." <u>Lujan</u>, 504 U.S. at 560. To satisfy Article III standing requirements, a plaintiff must demonstrate (1) an injury

in fact 2) the injury is fairly traceable to the challenged action of the defendant; and 3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000) (citation omitted). Whether a party has established the three elements of standing is an "inescapable threshold question." Advantage Media, L.L.C. v. City of Eden Prairie, 456 F.3d 793, 799 (8th Cir.2006). If a plaintiff lacks standing, "the district court has no subjectmatter jurisdiction" and the case must be dismissed. Faibisch v. Univ. of Minn., 304 F.3d 797, 801 (8th Cir. 2002); Fed. R. Civ. P. 12(h)(3).

"The Eleventh Amendment confirms the sovereign status of the States by shielding them from suits by individuals absent their consent." Digital Recognition Network, Inc. v. Hutchinson, 803 F.3d 952, 957 (8th Cir. 2015) (quoting Frew ex rel. Frew v. Hawkins, 540 U.S. 431, 437 (2004)). The Eleventh Amendment also bars suits brought against state officials if "the state is the real, substantial party in interest." Id. (quoting Pennhurst State Sch. & Hosp. v. Halderman, 465 U.S. 89, 101 (1984) (internal quotation marks omitted). That said, it has long been held that "a suit to enjoin a state official's enforcement of state

legislation on the ground that the official's action would violate the Constitution is not a suit against the State, and is thus not barred by the Eleventh Amendment, so long as the official has 'some connection with the enforcement of the act.'" Id. at 956-57 (citing and quoting Ex Parte Young, 209 U.S. 123, at 155-60 (1908)). This is so because unconstitutional state legislation is "void," and subsequent enforcement therefore "is a proceeding without the authority of, and one which does not affect, the state in its sovereign or governmental capacity." Ex Parte Young, 209 U.S. at 159.

"The questions of Article III jurisdiction and Eleventh Amendment immunity are related." <u>Hutchinson</u>, 803 F.3d at 957. To establish standing under Article III, the plaintiff must show a "causal connection between the state officials and the alleged injury." <u>Id.</u> The Eleventh Amendment likewise requires "some connection" between the officials and enforcement of the challenged state law. <u>Id.</u> The question here, then, is whether defendants have a sufficient connection to the enforcement of \$ 62J.96 to allow plaintiffs to proceed to the merits of their claims. The court concludes that they do not.

As the Attorney General argues, the legislature did not expressly empower the Attorney General to enforce § 62J.96, despite

granting the Attorney General enforcement authority in other sections of Chapter 62J. See Minn. Stat. § 62J.844 (empowering the Attorney General to sue civilly under the Prescription Drug Price Transparency Act, Minn. Stat. §§ 62J.841 to 62J.845). The legislature's silence as to enforcement in § 62J.96 is therefore significant. The legislature could have empowered the Attorney General to sue under § 62J.96 but chose not to. Further, there is no indication that the legislature ever contemplated empowering the Attorney General with such authority. See, e.g., AbbVie Am. Compl. ¶¶ 91-92.

The court is unpersuaded by plaintiffs' argument that the Attorney General is empowered to enforce § 62J.96 under its general constitutional powers or Minn. Stat. § 8.31, 5 as neither provide a sufficient connection between the statute and the Attorney General's general enforcement authority. See Hutchinson, 803 F.3d at 960-64 (state attorney general's "broad powers" to enforce state laws insufficient to meet the requisite causal connection to establish standing or Ex Parte Young's exception to sovereign

<sup>&</sup>lt;sup>5</sup> Section 8.31 authorizes the Attorney General to "investigate violations of the law of [Minnesota] respecting unfair, discriminatory, and other unlawful practices in business, commerce, or trade[.]" There is no indication that this provision is meant to be a catch-all to authorize the Attorney General to enforce any statute that does not name an enforcement entity.

immunity); see also Calzone v. Hawley, 866 F.3d 866, 870 (8th Cir. 2017) (same); Church v. Mo., 913 F.3d 736, 749-50 (8th Cir. 2019) (same).

As to the BOP, the court finds likewise. Although the legislature appears to have contemplated empowering the BOP to enforce § 62J.96, it did not do so. See Minn. H.F. 4991 and § 62J.96; see, e.g., AbbVie Am. Compl. ¶¶ 91-92. It did, however, empower the BOP with enforcement authority over other sections of Chapter 62J. See Minn. Stat. § 151.071. Again, the silence in § 62J.96 is meaningful, and in the case of the BOP, dispositive.

Also important here, the "Ex parte Young doctrine does not apply when the defendant official has neither enforced nor threatened to enforce the statute challenged as unconstitutional."

281 Case Comm. V. Arneson, 766 F.3d 774, 797 (8th Cir. 2014)

(internal citations and quotations omitted). There is no allegation that either defendant has enforced or threatened to enforce the statute. Indeed, defendants' position rests on the theory that they do not have the authority to do so. Plaintiffs argue that defendants must do more than say they have no present

<sup>&</sup>lt;sup>6</sup> The court trusts that defendants are earnest in the position they have taken in this case, and that they are not resting on purely semantic distinctions to evade litigation. The court would view any subsequent enforcement action under § 62J.96 by either defendant as contrary to the position they have taken in this case.

intention to enforce  $\S$  62J.96. The court disagrees. The Eighth

Circuit Court of Appeals has stated that the "failure to disavow

future prosecutions is not fatal to [a] claim of Eleventh Amendment

immunity." Minn. RFL Republican Farmer Labor Caucus v. Freeman,

33 F.4th 985, 992 (2022).

As a result, based on the finding of lack of standing and

Eleventh Amendment immunity, the court must dismiss this action.

CONCLUSION

Accordingly, based on above, IT IS HEREBY ORDERED that:

1. The motion to dismiss in AbbVie, Inc., et al. v. Ellison,

Case No. 24-cv-2605 [ECF No. 27], is granted;

2. The motion to dismiss in AstraZeneca Pharmaceuticals LP

v. Ellison, et al., Case No. 24-cv-2621 [ECF No. 31], is granted;

and

3. The above-entitled cases are dismissed.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: April 3, 2025

s/David S. Doty

David S. Doty, Judge

United States District Court

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